UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CITY OF LIVONIA EMPLOYEES' RETIREMENT SYSTEM, On Behalf of Itself and All Others Similarly Situated, Plaintiffs, vs. WYETH, ROBERT ESSNER, JOSEPH MAHADY, KENNETH MARTIN, BERNARD POUSSOT, ROBERT RUFFOLO, JR. and GINGER CONSTANTINE, Defendants.	Civil Action No. 07 CV 10329 (RJS)

MEMORANDUM OF LAW IN SUPPORT OF ALL DEFENDANTS'
MOTION TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT

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Pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) and the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u-4, *et seq* ("PSLRA"), Defendants Wyeth, Robert Essner, Bernard Poussot, Joseph Mahady, Kenneth Martin, Robert Ruffolo, Jr., M.D., and Ginger Constantine, M.D. move to dismiss Plaintiffs' Consolidated Complaint for Violations of the Federal Securities Laws in its entirety and with prejudice.

PRELIMINARY STATEMENT

This case is the most recent example of plaintiffs trying to manufacture a federal securities fraud claim out of statements about a new drug made by a pharmaceutical company during the federal regulatory approval process. As recently as last week, the Honorable Thomas P. Griesa, in granting a motion to dismiss, stated that courts will dismiss fraud claims where plaintiffs seek to exploit the vagaries of the regulatory process:

> The cases recognize that, particularly in the testing and development stage, the possible beneficial effects of a drug may be accompanied by adverse side effects, and there may be uncertainty as to how the risk-benefit balance ultimately turns out, and how it will be viewed by regulators. But if the management of the company releases positive reports about the drug to the public along the way which the management honestly believes to be true, and where there is no reckless disregard for truth, then that is not securities fraud, even though at a later point some event occurs which prevents the marketing of the drug or makes it necessary to take the drug off the market.

In re AstraZeneca Sec. Litig., No. 05 Civ. 2688, 2008 U.S. Dist. LEXIS 43680, at *42-43 (S.D.N.Y. June 3, 2008). Here, Defendants' statements amount to nothing more than optimism and forward-looking statements about a new drug going through the federal approval process. The statements were not guarantees. They were not falsely made. And they are not actionable.

This case concerns the drug Pristiq, which Wyeth is developing for two uses: the treatment of vasomotor symptoms ("VMS") or "hot flushes" in menopausal women, and the treatment of major depressive disorder ("MDD") in adults. In January 2007, Wyeth received an "approvable" letter from the Food and Drug Administration ("FDA") for Pristiq's MDD

indication. A year later, in February 2008, the FDA approved Pristiq for the treatment of MDD, and the drug has been available for that use in pharmacies since May 2008.

In July 2007, Wyeth received an approvable letter for Pristiq's VMS indication. Because of potential side effects observed in one of Wyeth's clinical trials, the letter required Wyeth to conduct an additional study before the FDA would approve Pristiq for the treatment of VMS. As a result, Pristiq is not expected to be eligible for FDA approval for VMS until sometime in 2010. Wyeth immediately announced receipt of the VMS approvable letter, and Wyeth's stock price fell.

Rewriting history, Plaintiffs now claim that Defendants made fraudulent statements about the chances of receiving FDA approval for the VMS indication and concealed data about the adverse events from one of four clinical studies submitted to the FDA ("Study 315"). But this is no more than an accusation that Defendants committed fraud based on hindsight, which courts routinely reject as a basis for alleging securities claims, especially in pharmaceutical cases involving new drug applications. Defendants believed at the time, and continue to believe, that Pristiq is a safe and effective treatment for VMS. While Defendants were obviously aware of (and disclosed) the results of Study 315 during the application process, they simply had no control over the way in which the FDA would respond to this data.

Indeed, Defendants repeatedly warned investors in their SEC filings and public statements that they could not control or guarantee regulatory actions and that the FDA may disagree with the Company about drug approval. Wyeth's 2005 Form 10-K warns that "[t]he development and commercialization of novel drugs requires significant expenditures with a low probability of success." Chepiga Aff. Ex. 1. Wyeth also told its shareholders:

> Notably, clinical trial data are subject to differing interpretations and, even when we view data as sufficient to support the safety and/or effectiveness of a product

> candidate or a new indication for an existing product, regulatory authorities may not share our views and may require additional data or may deny approval altogether.

Id. Moreover, even Plaintiffs *admit* that the regulatory environment for new drug approval was tightening and difficult to predict. The Complaint alleges that it was "well known" that Wyeth was "operating in a climate where markedly fewer drugs had been approved in the past five years as compared to the five years prior, and far more drugs were being rejected in the later stages of development than ever before." Compl. ¶ 10. Given this environment, Defendants cannot be faulted for not knowing what action the FDA would take, much less be accused of fraud.

As a legal matter, the Complaint fails to allege securities fraud under Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934 ("Exchange Act") and SEC Rule 10b-5 for four independent reasons. *First*, Defendants' statements were forward-looking and thus protected from liability. The statements regarding Pristiq's *future* were accompanied by cautionary language, constituted expressions of corporate optimism, and were not made with any knowledge that the statements were false or misleading. As such, they are entitled to immunity under both the PSLRA and the common law "bespeaks caution" doctrine. In addition, the safety data that Defendants allegedly hid was fully disclosed to the FDA, doctors, market watchers, and analysts. Indeed, during the Class Period an industry analyst expressly reported on Pristiq's adverse event data and their potential impact on the drug's approvability in an investor report entitled "WYE: How Will the 'New' FDA Handle Pristiq?" This information had no effect on the Company's stock price. Accordingly, this alleged omission cannot form the basis of a valid claim.

Second, Plaintiffs' scienter case is completely implausible. The Complaint asserts that Defendants acted in order to temporarily inflate Wyeth's stock price and maintain the

illusion that Pristiq was a blockbuster drug that would replace medicines losing patent protection. But it does not make any sense that Defendants would seek to address long-term revenue/pipeline concerns with the investment community by fraudulently touting a drug that it knew the FDA would act negatively on in the very near-term. Moreover, it is well established that general corporate motives to keep up a company's share price are inadequate as a matter of law to support a securities fraud claim. Plaintiffs also try to distort the facts regarding Defendants' stock sales to paint a picture of insider trading. The real figures indicate that neither the timing nor volume of Defendants' stock sales was suspicious or unusual. Moreover, the publicly-known facts about Defendants' stock holdings directly undermine Plaintiffs' "motive" allegations. The individual Defendants hold significant portions of their share holdings in long-term trusts (that they cannot access until retirement) and were awarded significant stock grants late in the Class Period that they could only exercise at the then existing price of $56/share. Given both of these facts, it would have been *detrimental* to Defendants' personal interests to temporarily inflate Wyeth's share price and set the Company up for an inevitable fall in July 2007. Under *Tellabs*' teaching, the Complaint fails because the alleged fraud scheme here does not make any sense.

Third, the Complaint does not allege loss causation. The alleged omissions regarding the Study 315 data could not have moved the market down in July, because they were actually disclosed to the market in May. That information had no material effect on the Company's stock price then and was fully absorbed into the market as of May 2007. The announcement that caused the Company's stock price to fall was Wyeth's July 24, 2007 press release indicating that the FDA issued an approvable letter, as opposed to an approval letter, for VMS. Defendants cannot be held responsible on fraud grounds for this loss: for months the

Company's disclosures had alerted the public that the FDA would be making a decision and that the Company could not control the outcome.

Fourth, the Complaint fails to plead essential elements of a claim under Section 20(a) for "control person" liability. Because the Complaint fails to assert a viable claim under Section 10(b) and Rule 10b-5, and does not give rise to any inference that Defendants culpably participated in the fraud, the Section 20(a) claim also fails.

STATEMENT OF FACTS

A. The Development of Pristiq

In December 2005, Wyeth submitted a New Drug Application ("NDA") to the FDA for approval for Pristiq for the treatment of MDD. Chepiga Aff. Ex. 2. On January 22, 2007, the Company received an "approvable" letter from the FDA.[1] *Id.* Ex. 3. The Company complied with the requirements laid out in the approvable letter, and in February 2008, received an FDA approval letter, approving Pristiq for the treatment of MDD in adults. *Id.* Ex. 4. In May 2008, Pristiq became fully available at pharmacies in the United States for the treatment of MDD.[2]

While the MDD application was progressing, Wyeth also sought approval from the FDA for a VMS indication for Pristiq. As part of its drug testing, Wyeth conducted several clinical trials, including four Phase III studies.[3] Compl. ¶¶ 5, 6; *see also* Chepiga Aff. Exs. 5-8.

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[1] The FDA, upon completing review of an NDA, will issue one of three letters: an approval letter, an approvable letter, or a not approvable letter. *See* 21 C.F.R. §§ 314.105, 314.110, 314.120 (2008). The FDA will issue an "approvable letter" when it wants "to indicate to the applicant that the application . . . is basically approvable providing certain issues are resolved." *Id.* § 314.110(a).

[2] *See* http://phx.corporate-ir.net/phoenix.zhtml?c=78193&p=irol-newsArticle&ID=1146178&highlight=MDD.

[3] For a drug manufacturer to receive approval from the FDA to market a new drug, the company must first conduct three phases of clinical trials "designed to assess the safety and efficacy" of the product. *In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 195-96 (S.D.N.Y. 2008). "During Phase I, the drug is administered to a small number of healthy participants in order to determine the proper dosage of the drug, to characterize its metabolism and excretion, and to identify acute side effects. Phase II trials include patients who suffer from the medical condition the drug is designed to treat; these trials are used to gather safety data and preliminary efficacy data. If the

In one of these four, Study 315, five women out of 689 (or 0.73%) suffered adverse cardiovascular events. Compl. ¶ 25. The Complaint correctly admits that Wyeth reported these events to the FDA promptly. *Id.* ¶ 27. Wyeth subsequently conducted three additional Phase III trials for VMS: Studies 319, 321, and 337. Chepiga Aff. Exs. 6-8.

On June 26, 2006, the Company submitted its NDA for Pristiq for the treatment of VMS, Chepiga Aff. Ex. 9, which contained all the safety data from Study 315, Compl. ¶ 25. Throughout the Class Period Wyeth regularly reported about Pristiq's status. *Id.* ¶¶ 24-27. Wyeth was hopeful about its chances of receiving approval, but also repeatedly cautioned the market that it had no control over the FDA's regulatory decision. For example, its 2006 Form 10-K, filed with the SEC in February 2007, stated:

> We have multiple product candidates in development and devote considerable resources to research and development activities, including clinical trials. These activities involve a high degree of risk and take many years. . . . Our product candidates in late-stage development include . . . PRISTIQ (for the treatment of vasomotor symptoms). . . . Our product development efforts with respect to any product candidate may fail or be delayed, and we may be unable to commercialize it or be delayed in commercializing it, for multiple reasons.

Chepiga Aff. Ex. 1.

On July 23, 2007, Wyeth received an approvable letter from the FDA for VMS (as it had for MDD, albeit for different reasons). *Id.* Ex. 10. The letter was not a rejection or denial of approval. In most instances an approvable letter serves "as a mechanism for resolving outstanding issues on drugs that are *about to be approved and marketed*." 21 C.F.R. § 314.110(a) (emphasis added). The letter stated that before the FDA could approve Pristiq for VMS, the Company would need to conduct an additional study to generate data about potential

results of Phase II trials suggest that the drug is safe and effective, Phase III trials investigate the effects of the drug in a much larger patient population." *Id.* at 196.

side effects. *Id.*; Compl. ¶ 42. The Company issued a press release disclosing the approvable letter on July 24. Its stock price subsequently fell.[4] Compl. ¶¶ 42, 47.

B. The Statements at Issue

The Complaint selectively isolates various forward-looking statements made in press releases, industry conferences, SEC filings, and conference calls between June 26, 2006 and July 24, 2007 (the "Class Period") as false and misleading. *See* Compl. ¶¶ 62-106. These statements pertain to the hoped-for FDA approval of Pristiq and its revenue-generating potential, if approved. The Complaint alleges that at the time these statements were made, Defendants were in possession of, but failed to disclose, the results of Study 315 and the exclusion criteria for Studies 319 and 321.[5] Compl. ¶¶ 31, 39, 67, 78, 84, 90, 95, 105.

Each of the press releases, SEC filings, conference presentations, and conference calls referenced in the Complaint heavily cautioned and made clear to investors that Defendants' statements about Pristiq were subject to risks and uncertainties that could cause actual results to differ. In other words, Wyeth was not (and given the nature of the regulatory process, could not be) promising any particular result or outcome. The following is example cautionary language from a Wyeth press release:

> The statements in this press release that are not historical facts are forward-looking statements based on current expectations of future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. **In particular, the statements in this press release regarding clinical data and/or the regulatory status of our**

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[4] The Complaint alleges that Wyeth has not started the new study called for by the FDA approvable letter and suggests that Defendants never believed in the approvability of Pristiq for VMS. Compl. ¶ 120. Plaintiffs are wrong. As indicated in Wyeth's SEC filings, the new study is on track, and Wyeth continues to plan for Pristiq's ultimate approval for the VMS indication. *See* Chepiga Aff. Ex. 3 ("We have been in discussions with the FDA regarding the approvable letter and the requested clinical trial. The trial currently under consideration would take 18 months or more to complete, and we expect that the study will begin in mid-2008, pending final FDA concurrence on the study protocol.").

[5] The Complaint alleges that Defendants manipulated and hid the exclusion criteria for Studies 319 and 321, but these exclusion criteria were reviewed and approved by the FDA, were established before the conclusion of Study 315, and were publicly disclosed well before the Class Period. *See* Chepiga Aff. Exs. 6, 7.

> **pipeline products are based on a preliminary analysis of the data and our expectations as to how that data will impact the regulatory approval process, which is subject to risks and uncertainties related to both the timing and success of regulatory approval.**

See Chepiga Aff. Ex. 1 (emphasis added). A chart of additional cautionary language found in press releases, conference calls, SEC filings, and conference presentations is attached hereto as Appendix A.

The Complaint also includes the erroneous allegation that Defendants did not disclose the Study 315 adverse event data or the exclusion criteria for Studies 319 and 321 during the Class Period. Compl. ¶¶ 31, 39, 67, 78, 84, 90, 95, 105. Because this allegation is contradicted by documents that the Court may appropriately consider on a motion to dismiss, the Court does not have to accept it as true. For example, prior to the Class Period, the exclusion criteria for Studies 319 and 321 were posted on an online clinical trials database maintained by the United States National Institute of Health.[6] *See* Chepiga Aff. Exs. 6, 7. Wyeth also reported on the efficacy and safety data for Study 315 at the 55th Annual Clinical Meeting of the American College of Obstetricians and Gynecologists ("ACOG") in May 2007, and this information was reported by a research analyst with the Prudential Equity Group ("Prudential").[7] *See id.* Exs. 11, 12. The Prudential analyst identified Study 315 safety data as a known risk, but not a risk that, in his view, was likely to interfere with FDA approval. Significantly, the disclosure of this information had no effect on Wyeth's stock price. *See id.* Ex. 13.

C. Defendants' Stock Sales

The Complaint names six individual defendants:

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6 The exclusion criteria for Study 319 were posted on November 18, 2005. Chepiga Aff. Ex. 6. The exclusion criteria for Study 321 were posted on September 16, 2005. *Id.* Ex. 7.

7 The Court may consider the Prudential analyst report in deciding Defendants' Motion to Dismiss. "Judicial notice can be taken of prior complaints and legal proceedings, press releases[,] news articles[,] and published analyst reports in determining what the market knew." *In re Zyprexa Prods. Liab. Litig.*, No. 07 Civ. 1310, 2008 WL 1923126, at *4 (E.D.N.Y. Apr. 30, 2008).

Name	**Position(s) Held**
Robert Essner	Chief Executive Officer Chairman of the Board
Joseph Mahady	Senior Vice President President, Global Business, Wyeth Pharmaceuticals
Kenneth Martin	Chief Financial Officer Vice Chairman
Bernard Poussot	President Chief Operating Officer Vice Chairman
Robert Ruffolo, Jr., M.D.	Senior Vice President President, Wyeth Research
Ginger Constantine, M.D.	Vice President of Women's Health

The Complaint alleges that the first five named defendants ("Selling Defendants") sold personal shares of Company stock during the Class Period. *See* Compl. ¶ 122. The Complaint does not allege that Dr. Constantine did so.

The majority of the Selling Defendants' stock sales were made in October 2006, over three months after the Company submitted the Pristiq NDA to the FDA and **over nine months before** receipt of the FDA's approvable letter. *See* Compl. ¶¶ 125-129. These sales also followed the Company's third quarter earnings call on Thursday, October 19, 2006, and were clustered during Tuesday through Friday of the following week (October 24 through October 27, 2006)—days when the Wyeth trading window for insiders was temporarily opened and insiders were permitted to sell stock. *See id.;* Chepiga Aff. Ex. 14. None of the Selling Defendants had sold stock in the five months preceding the third quarter earnings call.[8]

Mr. Martin also sold Company stock in April, May, and June 2007, immediately following his April 27, 2007 announcement that he was resigning from the Company. Compl. ¶ 127; Chepiga Aff. Ex. 15. Pursuant to the terms of the Company's stock incentive plan, Mr.

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[8] *See* Forms 4 filed with the SEC on behalf of Officers and Directors of Wyeth, pursuant to Section 16(a) of the Exchange Act, available at http://www.sec.gov/cgi-bin/browse-edgar?action=getcompany&CIK=0000005187&type=&dateb=&owner=only&start=0&count=100 ("SEC Website").

Martin would have lost any stock options that he did not exercise before he left. Chepiga Aff. Ex. 16. Dr. Ruffolo also made additional stock sales in May 2007, over two months before the FDA issued the approvable letter. Compl. ¶ 129.

Messrs. Essner, Mahady, and Poussot and Dr. Ruffolo sold less than 5%, 29%, 25%, and 45% of their holdings, respectively.[9] Mr. Martin, who was leaving the Company, sold 99% of his shares during the Class Period.[10] *See* SEC Website. These Defendants hold a significant number of shares in Wyeth's Restricted Stock Trust. At the end of the Class Period, Messrs. Essner, Mahady, Poussot, and Martin and Dr. Ruffolo owned 939,539 shares, 192,009 shares, 249,068 shares, 253,458 shares, and 211,397 shares, respectively, in the Restricted Stock Trust. *See id.* Pursuant to restrictions set forth in the Company's stock incentive plans, Defendants cannot access these shares until retirement. *See id.* On April 26, 2007, Messrs. Essner, Mahady, and Poussot and Dr. Ruffolo received substantial stock option grants (370,000 options, 108,000 options, 200,000 options, and 110,000 options, respectively) and substantial grants of performance share unit awards (192,000 unit awards, 49,940 unit awards, 112,500 unit awards, and 51,250 unit awards, respectively). *Id.* Ex. 16.

ARGUMENT

I. A HEIGHTENED PLEADING STANDARD APPLIES

On a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a court must accept as true all of the factual allegations in the complaint. *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007). The court need not, however, "accord '[l]egal

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[9] Although the Complaint alleges that Messrs. Essner, Mahady, and Poussot and Dr. Ruffolo sold 70%, 97%, 89%, and 90% of their Company stock holdings, respectively, Compl. ¶¶ 125-129, these numbers fail to take into account Defendants' vested stock options. When these options are properly considered, the percentages shrink to the numbers referenced above. *See* SEC Website. If unvested and restricted shares are factored in, the numbers shrink even further to less than **4%, 19%, 16%, and 27%,** respectively. *See id.*

[10] When unvested and restricted shares are factored in, this percentage drops to less than **72%**. *See* SEC Website.

conclusions, deductions, or opinions couched as factual allegations a . . . presumption of truthfulness.'" *In re NYSE Specialists Sec. Litig.*, 503 F.3d 89, 95 (2d Cir. 2007) (quoting *United States v. Bonanno Organized Crime Family of La Cosa Nostra*, 879 F.2d 20, 27 (2d Cir. 1989)). As the Supreme Court recently explained, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic v. Twombly*, 127 S. Ct. 1955, 1964-65 (2007). "[T]he touchstone for adequate pleading is plausibility. . . . Thus, materials properly before the court must provide grounds for more than mere speculation or suspicion that a plaintiff is entitled to the requested relief." *In re Take-Two Interactive Sec. Litig.*, No. 06 Civ. 803, 2008 WL 1757823, at *6 (S.D.N.Y. Apr. 16, 2008); *see also ATSI*, 493 F.3d at 98.

Securities fraud claims are subject not only to these universal pleading requirements, but also to the heightened pleading standards imposed by Federal Rule of Civil Procedure 9(b) and the PSLRA. Rule 9(b) dictates that the "[i]n alleging fraud . . . a party must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Pursuant to the PSLRA, in an action for money damages requiring proof of scienter, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2) (2008). "The Supreme Court has . . . instructed that a complaint should survive a motion to dismiss 'only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.'" *In re FBR Inc. Sec. Litig.*, 544 F. Supp. 2d 346, 352 (S.D.N.Y. 2008) (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2510 (2007)).

In deciding a motion to dismiss, a court may consider the complaint, "statements or documents incorporated into the complaint by reference, legally required public disclosure

documents filed with the SEC, and documents possessed by or known to plaintiff and upon which it relied in bringing suit." *ATSI*, 493 F.3d at 98. The court may also consider "matters subject to judicial notice." *Take-Two*, 2008 WL 1757823, at *6 (citing *Tellabs*, 127 S. Ct. at 2509).

II. THE COMPLAINT SHOULD BE DISMISSED BECAUSE PLAINTIFFS HAVE NOT ALLEGED ANY ACTIONABLE STATEMENTS OR OMISSIONS

To state a Section 10(b) and Rule 10b-5 claim, a plaintiff must allege that the defendant "(1) made misstatements or omissions of material fact, (2) with scienter, (3) in connection with the purchase or sale of securities, (4) upon which plaintiff relied, and (5) that plaintiff's reliance was a proximate cause of its injury." *ATSI*, 493 F.3d at 105. Plaintiffs fail to state a claim because Defendants' alleged statements and omissions are not actionable. Defendants' statements are protected from liability under both the PSLRA's statutory safe harbor provision and the common law "bespeaks caution" doctrine. Defendants' alleged omissions were disclosed to the market and are immaterial as a matter of law.

A. Defendants' Forward-Looking Statements Are Protected From Liability Under the PSLRA and the "Bespeaks Caution" Doctrine

Pursuant to the PSLRA, forward-looking statements that prove to be incorrect are not actionable if they fall into any one of three "safe harbor" categories outlined in the statute:

> The <u>first</u> protects forward-looking statements when they are identified as forward-looking and "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." . . . The <u>second</u> statutory safe harbor protects forward-looking statements when they are immaterial. . . . The <u>third</u> safe harbor protects forward-looking statements unless the plaintiff can prove that the statement "was made with actual knowledge by that person that the statement was false or misleading."

Kemp v. Universal Am. Fin. Corp., No. 05 Civ. 9883, 2007 WL 86942, at *11 (S.D.N.Y. Jan. 10, 2007) (quoting 15 U.S.C. § 78u-5(c)). "[The] safe harbor [provision] is complemented by the

judicially-created 'bespeaks caution' doctrine, under which 'alleged misrepresentations are immaterial as a matter of law [if] it cannot be said that any reasonable investor could consider them important in light of adequate cautionary language.'" *Id.* (quoting *In re QLT Inc. Sec. Litig.*, 312 F. Supp. 2d 526, 532 (S.D.N.Y. 2004)). Courts routinely find that statements issued by drug manufacturers about the likelihood of FDA approval of a new drug—like the ones alleged here—are non-actionable forward-looking statements. *See, e.g.*, *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. 04 Civ. 1030, 2005 WL 4161977 (D. Colo. Oct. 20, 2005); *In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 557-59 (S.D.N.Y. 2004); *In re Viropharma, Inc. Sec. Litig.*, No 02 Civ. 1627, 2003 WL 1824914 (E.D. Pa. Apr. 7, 2003); *In re Connetics Corp. Sec. Litig.*, No. 07-02940, 2008 WL 269467 (N.D. Cal. Jan. 29, 2008). Defendants' statements are protected from liability under all three categories of the PSLRA's safe-harbor provision and the "bespeaks caution" doctrine.

The PSLRA's definition of "forward-looking statement" is broad. It includes "plans and objectives of management for future operations, including plans or objectives relating to . . . products or services;" "projection of revenues;" "statement[s] of future economic performance;" and "assumptions underlying or relating to" any forward-looking statement. 15 U.S.C. § 78u-5(i)(1) (2008); *see also Fellman v. Electro Optical Sys. Corp.,* No. 98 Civ. 6403, 2000 WL 489713, at *4-5 (S.D.N.Y. Apr. 25, 2000) (statements that a company "estimates a long-term potential market size" and "is poised to become" a leader and that its "revenues and earnings should build very rapidly" are "clearly" forward-looking). A copy of the pertinent section of the PSLRA is attached hereto as Appendix B. Defendants' statements, which pertain to the hoped-for FDA approval of Pristiq, its future uses, and its revenue-generating potential,

fall squarely within this expansive definition of "forward-looking." Examples of Wyeth's forward-looking statements include:

"[W]e predict that Pristiq has the potential to exceed $2 billion in peak sales." (Compl. ¶ 74)
"FDA action . . . is anticipated in April 2007. Pristiq is expected to provide significant relief of hot flushes." (Compl. ¶ 77)
"If approved, Pristiq will be the first non-hormonal treatment indicated for relief of VMS." (Compl. ¶ 77)
"[Pristiq is] positioned also to be the first non-hormonal treatment approved for vasomotor symptoms." (Compl. ¶ 87)

See also Noble, 2005 WL 4161977, at *9 ("Projections about the likelihood of FDA approval are forward-looking statements. . . and as such fall under the PSLRA's safe harbor rule.").

The first part of the PSLRA's safe harbor rule protects forward-looking statements that are accompanied by cautionary language "identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. § 78u-5(c)(A)(i) (2008). The United States District Court for the District of Colorado held that **a pharmaceutical company cannot be held liable for projections about FDA approval of a new drug where the company warns investors that it is not making any guarantees**:

> The Company's cautionary statements addressed the possibilities that test data could be subject to varying interpretations, that the Company might not be able to demonstrate efficacy, that a second Phase 3 trial might be necessary, and that FDA approval might be delayed or not obtained at all. These statements are sufficient to inform a reasonable investor about the uncertainties surrounding FDA approval. Investors who purchased [Company] stock during the Class Period had notice that a risk of investing was that the FDA might not approve [the drug] in the near term or ever.

Noble, 2005 WL 4161977, at *9 (citation omitted).

Here, each of Defendants' statements was accompanied by a substantial warning. Cautionary language was written in each press release, SEC filing, and conference presentation and read aloud at each conference call. For example:

> The statements in this press release that are not historical facts are forward-looking statements based on current expectations of future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. **In particular, the statements in this press release regarding clinical data and/or the regulatory status of our pipeline products are based on a preliminary analysis of the data and our expectations as to how that data will impact the regulatory approval process, which is subject to risks and uncertainties related to both the timing and success of regulatory approval.**

Chepiga Aff. Ex. 1 (emphasis added). Defendants also stated:

> Our product development efforts . . . may fail or be delayed . . . for multiple reasons, including . . . [i]nsufficient clinical trial data to support the safety and/or effectiveness of the product candidate [and] our failure to obtain, or our experiencing delays in obtaining, the required regulatory approvals for the product candidate.

Id. This language warned investors that various events could prevent or delay FDA approval of Pristiq for VMS. As a result, Defendants' statements are protected from liability under the first category of the PSLRA's safe harbor provision.

Defendants' statements are also protected under the second safe harbor category. Irrespective of any cautionary language, the PSLRA protects forward-looking statements that are "immaterial." *See* 15 U.S.C. § 78u-5(c)(1)(A)(ii) (2008). It is well-settled in the Second Circuit that "[m]ere puffery or generalized expressions of optimism are immaterial as a matter of law." *Kemp*, 2007 WL 86942, at *11; *see also Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004) ("[E]xpressions of puffery and corporate optimism do not give rise to securities violations. Up to a point, companies must be permitted to operate with a hopeful outlook.") (citation omitted); *QLT*, 312 F. Supp. 2d at 532. "Likewise, statements of opinion are insufficient to form the basis of a misrepresentation or omission complaint under § 10(b)." *Bristol-Myers*, 312 F. Supp. 2d at 557.

Courts have specifically held that statements regarding the approval prospects and projected success of a new drug constitute non-actionable puffery, opinion, and corporate

optimism. In *Bristol-Myers*, officers of a major drug manufacturer issued several positive statements about the likely FDA approval of a new drug. 312 F. Supp. 2d at 557-59. Among the statements issued by the company were that the drug had "real blockbuster potential" and "represent[ed] one of the most exciting advances in cancer medicine." *Id.* One company executive said: "I don't think it's *likely* at all that this drug won't get approved." *Id.* Ultimately the FDA failed to review the company's drug application because the company's data were insufficient. *Id.* at 554. In rejecting investors' claim for securities fraud, the court stated:

> [The] statement regarding FDA approval cannot be considered a guarantee of FDA approval or otherwise false or misleading. It predicts the action the Company would take in the event the [application] was not approved and it expresses personal optimism about regulatory events not under the Company's control. Any reasonable investor reading these statements, or any of the other statements regarding [the drug] complained of by Plaintiffs would recognize that the Defendants could not and did not guarantee that [the drug] would be approved by the FDA, either in the near term or at all.

Id. at 558; *see also Viropharma*, 2003 WL 1824914, at *6 ("The . . . report that merely stated the company's belief that [the drug] was on a strong track to approval is . . . immaterial because **investors should not rely on a company's predictions about future actions of independent government agencies**.") (citation omitted) (emphasis added).

Defendants' statements are of the same sort. Indeed, they are far less bullish than statements that have been found non-actionable in the cases cited above:

- "[W]e think we have a package that could warrant approvability." (Compl. ¶ 65)
- "[W]e think [Pristiq] has very, very significant upside potential." (Compl. ¶ 94)
- "We expect these products will contribute to the growth of Wyeth for years to come." (Compl. ¶ 97)

These and other statements like them fall within the second category of the PSLRA's safe harbor rule and are not actionable under the securities laws.

Defendants' statements are also protected under the third category of the PSLRA's safe harbor provision. Forward-looking statements are non-actionable where "plaintiffs fail to prove that they were made with knowledge that the statements were false or misleading." *In re Veeco Instruments, Inc. Sec. Litig.*, 235 F.R.D. 220, 235 (S.D.N.Y. 2006). Statements about whether the FDA will approve a new drug (an outcome over which pharmaceutical companies have no control) fall within these parameters. As one court explained:

> [The company] was forecasting a future event. Any alleged deficiencies in the testing procedures do not indicate that [the company's] prediction of an FDA approval date was false when made. Instead, the company could have known of problems in the testing procedures, planned to remedy those deficiencies, and still thought it would achieve FDA approval by the estimated date. Clearly, Defendants' prediction of a date for a regulatory decision over which they did not have control, made that far in advance, for a drug that was still in the testing stages, could not carry a guarantee of accuracy or reliability.

In re Syntex Corp. Sec. Litig., 95 F.3d 922, 930 (9th Cir. 1996). Plaintiffs cannot point to anything indicating that Defendants knew at the time of their statements that the FDA would not approve the drug in July 2007. The allegations in the Complaint demand the opposite conclusion. If Defendants believed that the Study 315 safety data would preclude FDA approval of the drug, they would not have continued to invest time and money in Studies 319 and 321. As such, Defendants' statements are not actionable under Section 10(b) and Rule 10b-5.

Finally, Defendants' statements are protected from liability under the judicially-created "bespeaks caution" doctrine, which preceded, but was not supplanted by, the PSLRA. *See Gavish v. Revlon, Inc.*, No. 00 Civ. 7291, 2004 WL 2210269, at *21 (S.D.N.Y. Sept. 30, 2004). Pursuant to the "bespeaks caution" doctrine, "alleged misrepresentations [that] are accompanied by meaningful cautionary statements are considered immaterial as a matter of law." *Veeco*, 235 F.R.D., at 235. As discussed previously, each of Defendants' statements was

accompanied by substantial cautionary language. *See* Appendix A. This language specifically warned investors that FDA approval of Pristiq for VMS was subject to risks and uncertainties. For all of the above-stated reasons, Defendants' statements are not actionable under the securities laws.

B. Any Alleged Omissions Were Disclosed During the Class Period and Are Immaterial as a Matter of Law

A plaintiff who bases a securities fraud claim on an omission must establish that the alleged omission (1) was not disclosed and (2) is material. Here, Plaintiffs fail to do either.

Where an alleged omission was disclosed to the market, an investor cannot maintain a claim for securities fraud. *See In re Pfizer, Inc. Sec. Litig.*, No. 06 Civ. 14199, 2008 WL 540120, at *6 (S.D.N.Y. Feb. 28, 2008); *see also In re Progress Energy, Inc. Sec. Litig.*, 371 F. Supp. 2d 548, 552-53 (S.D.N.Y. 2005) ("[I]t is indisputable that there can be no omission where the allegedly omitted facts are disclosed. . . . [T]he securities laws do not require disclosure of information that is publicly known.") (citations omitted). "[T]he relevant question is not whether the market 'truly knew' any specific piece of information, but [only] whether the information was 'reasonably available.' *Starr v. Georgeson S'holder, Inc.*, 412 F.3d 103, 110 (2d Cir. 2005).

The Complaint repeatedly alleges that Defendants omitted four pieces of information: (a) that use of Pristiq in Study 315 was associated with hepatic and cardiovascular side effects; (b) that 27 women in the treatment group of Study 315 allegedly suffered severe adverse events ("SAEs") during the therapy or post-therapy periods; (c) that the incidence of hypertension in the treatment group of Study 315 increased as the dose of Pristiq increased; and (d) that Defendants excluded from two later studies (Studies 319 and 321) women with a history

of heart attack, chest pains, elevated blood pressure and blood clots.[11] Compl. ¶¶ 67, 78, 84, 90, 95, 105. Contrary to Plaintiffs' allegations, this information was disclosed to the market. Wyeth openly reported information about its exclusion criteria for Studies 319 and 321 on the well-known clinical trials website in *2005*—a year-and-a-half before the Class Period even started—and reported detailed efficacy and safety information from Study 315 at the 55th Annual Clinical Meeting of the American College of Obstetricians and Gynecologists. *See* Chepiga Aff. Exs. 6, 7, 11. The Study 315 data were subsequently discussed in an analyst report issued by Prudential released on May 21, 2007.[12] Chepiga Aff. Ex. 12. That report is particularly telling. It discussed both the adverse event data of Study 315 and the differing eligibility criteria for Study 319 and Study 321. The analyst focused shareholders on the uncertainties associated with Pristiq's approval, wondering "whether a seemingly cautious FDA could cause a wrinkle in the pending regulatory outcome." *Id.* The report conjectured on possible outcomes:

> The worst-case scenario would be a rejection of Pristiq for VMS, or substantial additional delays, but the odds of this appear low. A more realistic worst case scenario, in our view, is that Pristiq's labeling has safety warnings that impact its commercial potential, or that in the absence of a label change prescribers/payors/patients at least view the product with less enthusiasm. . . .

Id. The analyst, with full knowledge of Study 315, ultimately concluded that FDA approval was likely.[13] *Id.*

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[11] Defendants note that Plaintiffs' recitation of these alleged "omissions" is itself flawed, and the Court need not accept Plaintiffs' characterizations as true. First, Study 315 had only five patients with cardiovascular events. Chepiga Aff. Ex. 12. Second, the 27 SAEs alleged by Plaintiffs include other events. Third, the FDA did not cite to hypertension as a basis for issuing an approvable letter instead of an approval letter, so this issue is immaterial. Chepiga Aff. Ex. 10. Fourth, as already mentioned, the exclusion criteria for Studies 319 and 321 were not created as a "reaction" to Study 315's outcomes. *See* Chepiga Aff. Exs. 6, 7. Rather, Studies 319 and 321 were designed as part of Wyeth's overall clinical plan for Pristiq testing; their exclusion criteria were reviewed and approved by the FDA; and the studies began before the results of Study 315 were known.

[12] The lead author of the report is Tim Anderson, M.D. Dr. Anderson covers the pharmaceutical industry regularly, including Schering-Plough, Eli Lilly, Forest Laboratories, Merck &Co., Bristol-Myers Squibb, Pfizer, Inc., GlaxoSmithKline plc, AstraZeneca, and Novartis AG. Chepiga Aff. Ex. 12.

[13] Dr. Anderson's report for Prudential shows that an analyst provided with the information that Plaintiffs allege was not disclosed reached the same conclusions as the Company—namely, that the Study 315 data would not

The market's lack of reaction to the May 21, 2007 analyst report indicates that the alleged omissions are immaterial. It is widely recognized that when a company's stock price, operating in an efficient market, is unaffected by the disclosure of information, the omitted facts are immaterial as a matter of law.[14] *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1425 (3d Cir. 1997) ("In the context of an 'efficient' market, the concept of materiality translates into information that alters the price of the firm's stock."). Here, the Complaint admits that "throughout the Class Period, Wyeth traded in an efficient market on the New York Stock Exchange." Compl. ¶ 51. In addition, following the release of the May 21, 2007 analyst report, in which the allegedly withheld safety data were disclosed, Wyeth's stock price stayed essentially the same, as shown in the chart below. (Note that May 19 and 20, 2007 was a weekend.)

Date	**Wyeth Stock Price**
May 17, 2007	$56.08
May 18, 2007	$56.38
May 21, 2007	$58.41
May 22, 2007	$58.42
May 23, 2007	$58.29
May 24, 2007	$58.17

adversely affect FDA approval. Chepiga Aff. Ex. 12. Plaintiffs' argument that everyone should have reached the opposite conclusion underscores that their complaint attempts to assert a fraud based on hindsight.

[14] Information disseminated in an analyst report is considered "public." *See In re Dynex Capital, Inc. Sec. Litig.*, No. 05 Civ. 1897, 2006 WL 314524, at *6 (S.D.N.Y. Feb. 10. 2006) ("[T]he analyst reports demonstrate that there was information available to the public."); *Zyprexa*, 2008 WL 1923126, at *39 (E.D.N.Y. Apr. 30, 2008) ("Based on extensive available medical research, media coverage, court filings, regulatory decisions and *securities analyst reports*, an investor of ordinary intelligence should have been aware of [various facts about the drug].") (emphasis added); *United States v. Cusimano*, 123 F.3d 83, 89 n.6 (2d Cir. 1997) ("[I]nformation is nonpublic if it is not available to the public through such sources as press releases, Securities and Exchange Commission filings, trade publications, *analysts' reports*, newspapers, magazines, rumors, word of mouth or other sources.") (emphasis added). Information in analysts' reports is deemed to be absorbed into the market. *See In re Initial Pub. Offering Sec. Litig.*, 383 F. Supp. 2d 566, 579 (S.D.N.Y. 2005) ("The efficient market hypothesis holds that public information about a security is *immediately* incorporated into share prices.") (emphasis added).

Chepiga Aff. Ex. 13. As a matter of law, the alleged "omissions" are thus immaterial and not actionable under the securities laws.[15]

III. PLAINTIFFS HAVE NOT ADEQUATELY ALLEGED SCIENTER

Plaintiffs' Section 10(b) and Rule 10b-5 claim is also subject to dismissal because Plaintiffs fail to plead that Defendants acted with scienter. The law dictates that "the complaint shall, with respect to each act or omission alleged . . . state *with particularity* facts giving rise to a *strong inference* that the defendant acted with . . . intent to deceive, manipulate, or defraud.'" *ATSI*, 493 F.3d at 99 (quoting 15 U.S.C. § 78u-4(b)(2)) (emphasis added). A plaintiff "may satisfy this requirement by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *Id.*

An inference of scienter is strong only if it is "**cogent** and **at least as compelling as any opposing inference** one could draw from the facts alleged." *Tellabs*, 127 S. Ct. at 2510 (emphasis added); *see also In re Bayou Hedge Fund Litig.*, 534 F. Supp. 2d 405, 415 (S.D.N.Y. 2007). This inquiry is "inherently comparative;" in determining whether the pleaded facts give rise to a strong inference of scienter, the court must take into account "plausible nonculpable explanations for the defendant's conduct." *Id.* An inference that is merely "plausible" or "reasonable" is insufficient and will not survive a motion to dismiss:

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[15] The May 21, 2007 analyst report thus underscores three important points: (a) the allegedly hidden information was in fact disclosed; (b) the market fully understood the risks and uncertainties associated with the

Case	**Holding**
ATSI Communications, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 104 (2d Cir. 2007)	Granted defendants' motion to dismiss because there was "a 'plausible nonculpable explanation' for the defendants' actions . . . more likely than any inference that the defendants intended to manipulate the market . . ."
In re Take-Two Interactive Sec. Litig., No. 06 Civ. 803, 2008 WL 1757823, at *24 (S.D.N.Y. Apr. 16, 2008)	Dismissed plaintiffs' securities fraud claim, because "against [plaintiffs'] tenuous showing of [defendant's] scienter, the Court must weigh nonculpable explanations for [defendant's] conduct," and plaintiffs' "allegations undermine any sinister reading of [that] conduct."
City of Brockton Retirement Sys. v. Shaw Group Inc., 540 F. Supp. 2d 464, 475 (S.D.N.Y. 2008)	Dismissed plaintiffs' complaint for failure to raise an inference of scienter "as compelling as the competing inference" that defendants did not know their statements were false.

As discussed below, Plaintiffs fail to plead facts giving rise to a plausible inference of scienter.

A. Defendants' Alleged Scheme to Defraud Is Implausible and Less Compelling Than a Nonculpable Explanation for Defendants' Conduct

Although it is possible for a plaintiff to plead scienter by alleging facts showing a defendant's motive and opportunity to commit fraud, an alleged motive is insufficient unless it meets certain criteria. First, the motive must be coherent; "allegations of irrational motive cannot support a fraud claim." *Hampshire Equity Partners II, L.P. v. Teradyne, Inc.*, No. 04 Civ. 3318, 2005 WL 736217, at *3 (S.D.N.Y. Mar. 30, 2005); *see also In re Geopharma, Inc. Sec. Litig.*, 411 F. Supp. 2d 434, 446 (S.D.N.Y. Jan. 27, 2006) ("[T]he tenuous plausibility of the alleged scheme substantially weakens the overall strength of plaintiffs' scienter allegations."). Second, "motives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from the fraud." *Geopharma*, 411 F. Supp. 2d at 441 (citing *Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir. 2001)). Third, pursuant to *Tellabs*, even where a plaintiff alleges a plausible, personal motive, a claim must be dismissed where the alleged motive is less compelling than

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FDA approval process; and (c) the Study 315 safety data had no effect on the Company's stock price.

competing nonculpable explanations for defendants' behavior. *See. e.g., Take-Two*, 2008 WL 1757823, at *22-24. Here, Defendants' alleged motive fails on all three fronts: it is inconsistent, ordinary, and less compelling than a nonculpable explanation for Defendants' behavior.

<u>Incoherent Theory</u>

Defendants' alleged liability is based on the assumption that Defendants knew that the Study 315 safety data would prevent or delay FDA approval of Pristiq and intentionally withheld this information from investors in order to temporarily increase Wyeth's stock price until the FDA announced its decision. This scheme is nonsensical. According to the Complaint, Defendants chose to conceal information because "[h]ad defendants fully disclosed this information . . . it would have cast serious doubts on the chances of FDA approval . . . and damaged the Pristiq franchise." Compl. ¶ 22. However, if Defendants knew that the FDA would not approve Pristiq, the damage to Wyeth's franchise would not be prevented, only delayed. The Complaint itself alleges that Defendants *disclosed* the Study 315 data to the FDA. *See id.* ¶¶ 25-27. And it would have been illogical for Defendants to continue to invest large amounts of time and money in Studies 319 and 321 if they knew that the FDA would not approve Pristiq for VMS. Moreover, Defendants knew that details of Pristiq's safety profile would become public when the FDA issued its decision; it makes no sense for Defendants to temporarily hide this information and thereby risk the exact liability for failing to disclose it that Plaintiffs are trying to assert here.

Indeed, Defendants would have been acting *against their own economic self-interest* to intentionally submit an NDA to the FDA that they knew would not receive approval. Defendants hold large amounts of stock in a Restricted Stock Trust (which they cannot access until retirement), and thus have strong incentive to maximize long-term rather than short-term

Company stock price. *See* SEC Website. Defendants were also granted a substantial number of stock options on April 26, 2007. Chepiga Aff. Ex. 16. These options could only be exercised at the then-existing price of $56/share. Intentionally inflating the stock price prior to a grant of options runs counter to the Individual Defendants' self-interest. Defendants needed the share price to *rise* after the options grant in order for their options to have any value. Concocting a scheme to inflate the share price before an options grant in April 2007, knowing that it would fall in July 2007, would only work to Defendants' detriment. Defendants' alleged motive is thus incoherent and fails to raise a strong inference of scienter. *See Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1130 (2d Cir. 1994) (finding plaintiff's alleged motive insufficient to survive a motion to dismiss because "[i]t is hard to see what benefits accrue from a short respite from an inevitable day of reckoning").

Ordinary Corporate Motive

Second, the Complaint alleges the sort of universal corporate motive that courts routinely find insufficient to support a fraud claim. It is well-settled that:

> [A]lthough maintaining the appearance of corporate profitability . . . will involve benefit to the corporation, allegations that defendants were motivated by those desires in connection with making allegedly false statements are not sufficient to support an inference of scienter. . . . **[E]very publicly-held corporation desires its stock to be priced highly by the market and to hold that allegations to that effect were sufficient motive would be to render the motive requirement meaningless**.

Bristol-Meyers, 312 F. Supp. 2d at 560 (citation omitted) (emphasis added). Courts have specifically employed this principle to dismiss claims for securities fraud in cases involving new drug trials. In *Pfizer*, a major drug manufacturer halted clinical trials of a developmental drug after issuing positive statements about the drug's safety and efficacy. 2008 WL 540120, at *2. Plaintiffs attempted to plead motive for fraud by alleging that Pfizer wanted to "assure the financial community of the existence of a new blockbuster drug." *Id.* at *8. The Court held that

this alleged motive was insufficient to raise an inference of scienter: "This is not a unique motive. Rather, it is a way of saying, in a manner tailored to a pharmaceutical company, something that is true for all profit enterprises—each has an incentive to portray the likelihood that it will continue to prosper." *Id.*

Likewise, in *Bristol-Myers*, plaintiff tried to allege motive based on the company's desire to "maintain a façade of future potential" for its drug pipeline and to "address potential concerns about patent expirations." 312 F. Supp. 2d at 560-61. The court held that these motives were "nothing more than ordinary and prudent corporate desires" and thus insufficient to establish scienter under Section 10(b). *Id.*; *see also In re Bayer AG Sec. Litig.*, 03 Civ. 1546, 2004 WL 2190357, at *14 (S.D.N.Y. Sept. 30, 2004).

Plaintiffs' Complaint is replete with the same clichés that investors have pleaded in numerous securities cases against drug manufacturers—clichés that courts repeatedly find insufficient to plead scienter:

Motives Courts Find Insufficient	**Allegations Here**
"[A]ssure the financial community of the existence of a new blockbuster drug" (*Pfizer*)	Bring a "blockbuster" drug to market in time to offset declining revenues (Compl. ¶ 21)
"'[M]aintain a façade of future potential' for the Company's drug pipeline" (*Bristol-Myers*)	"[P]romote Wyeth's drug pipeline" (Compl. ¶ 16)
"Address potential concerns about patent expirations" (*Bristol-Myers*)	Face "loss of income from drugs set to go off-patent" (Compl. ¶ 11)
"[M]ake it appear that the future of the Company was more promising" (*Bristol-Myers*)	"[S]ustain growth and profitability" (Compl. ¶ 9)

Plaintiffs' allegations are merely alternative ways of saying that the Company wanted to maintain the appearance of profitability. As such, they do not give rise to an inference of scienter, much less a strong one.

<u>Unconvincing Motive Inference</u>

Finally, Defendants' alleged "scheme" falls far short of passing muster under *Tellabs*. As discussed above, *Tellabs* requires a court to take into account plausible, nonculpable explanations for a defendant's conduct. Where the inference of scienter is less compelling than an inference of innocent conduct, a plaintiff's Section 10(b) claim will fail as a matter of law. Here, the allegations in the Complaint overwhelmingly suggest that Defendants, rather than hiding material information as part of an elaborate scheme to inflate Wyeth's stock price, were simply hopeful about the chances of FDA approval of Pristiq for VMS. Importantly, the Company received an FDA approvable letter for MDD during the Class Period and was therefore confident that the drug was on track for MDD approval, which it received in February 2008. Compl. ¶¶ 18, 86; Chepiga Aff. Ex. 3. *See AstraZeneca*, 2008 U.S. Dist. LEXIS 43680, at *47 ("The approval of [the drug] in Europe for some uses, made it not unreasonable for defendants to believe in their product."). Moreover, as discussed above, it would be a very strange case of concealment and fraud where Defendants fully disclosed the Study 315 safety data to the FDA, to doctors, to market watchers and to analysts. *See* Compl. ¶ 25; Chepiga Aff. Ex. 11. Even if the Court were to find that the Complaint gives rise to a *reasonable* inference of fraud (which it does not), this inference is patently less compelling than the inference that Defendants were hopeful but mistaken that Pristiq would be approved for VMS (as it was for MDD) and did not know that the FDA would view the safety data from Study 315 as necessitating an additional pre-approval clinical trial.

B. Plaintiffs Fail to Allege That Defendants' Stock Sales Were Sufficiently "Suspicious" or "Unusual" to Give Rise to a Strong Inference of Scienter

Plaintiffs also allege that Defendants' scienter is evidenced by a "series of coordinated sales during the class period," in which "defendants Essner, Mahady, Martin,

Poussot and Ruffolo dumped more than 1.55 million shares of their Wyeth stock for insider trading proceeds of $83.82 million." Compl. ¶ 40. The Complaint's reference to Defendants' stock sale "proceeds" is misleading. Although Defendants were paid $83.82 million in exchange for selling their shares, Defendants initially purchased these shares for $65.98 million. *See* SEC Website. Thus the net proceeds on Defendants' Class Period stock sales were $17.84 million. *Id.* More importantly, "executive stock sales, standing alone, are insufficient to support a strong inference of fraudulent intent." *Bristol-Myers*, 312 F. Supp. 2d at 561. "For insider sales to raise an inference of improper motive, they must be 'suspicious or unusual.'" *In re KeySpan Corp. Sec. Litig.*, 383 F. Supp. 2d 358, 381-82 (E.D.N.Y. 2003). To determine whether particular stock sales are "suspicious or unusual," courts examine a number of factors, including the number of insiders selling at the time; the amount and percentage of stockholdings sold and the profit from the sales; the timing of the sales; and any pattern of prior sales. *See In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 74-75 (2d Cir. 2001). When these factors are considered, it is clear that the Complaint does not give rise to a strong inference of scienter.

Although the Complaint alleges that Messrs. Essner, Mahady, Martin, and Poussot and Dr. Ruffolo sold stock during the Class Period, it neglects to mention that eleven of the Company's twelve directors who were required to file public records of their stock holdings did not sell any stock during that same period of time. *See* SEC Website. This fact detracts from any possible inference of scienter. *See Keyspan*, 383 F. Supp. 2d at 383-84 (citations omitted) ("Additional factors weigh against an inference of scienter. . . . [E]ight other . . . officers who were required to file public records of their stock holdings—and who are not named as defendants—did not sell any stock.").

More importantly, the circumstances of the individual Defendants' stock sales do not suggest a "fraud." The timing of a stock sale is considered suspicious or unusual only when it is "calculated to maximize personal benefit from inside information." *Ressler v. Liz Claiborne*, 75 F. Supp. 2d 43, 60 (E.D.N.Y. 1999). Also, "[l]arge dollar amounts alone typically do not suffice to establish motive." *Id.* Rather, courts are instructed to consider the percentage of stockholdings sold. *Keyspan*, 383 F. Supp. 2d at 382. As discussed below, by these standards, none of the individual Defendant's stock sales was suspicious or unusual.

1. Plaintiffs Do Not Allege That Dr. Constantine Sold Company Stock

Plaintiffs do not allege that Dr. Constantine sold any Company stock during the Class Period. As a result, the Complaint's allegations regarding insider sales do not give rise to a strong inference that Dr. Constantine acted with scienter.

2. Messrs. Essner's, Mahady's, and Poussot's and Dr. Ruffolo's Stock Sales Were Not Suspicious or Unusual

The Complaint alleges that four other Defendants sold stock in October 2006 and that Dr. Ruffolo also sold company stock in May 2007. Compl. ¶¶ 125-28. Neither the timing nor amount of these sales is indicative of fraudulent intent.

First, with regard to timing, Messrs. Essner, Mahady, and Poussot and Dr. Ruffolo sold their shares: (1) after Defendants had allegedly been issuing false and misleading statements for over three months; and (2) **nine months** before the Company issued a press release announcing receipt of the FDA approvable letter.[16] *See* Compl. ¶ 62; Chepiga Aff. Ex. 10. Courts find timing such as this insufficient, as a matter of law, to create a strong inference of scienter. *See Keyspan*, 383 F. Supp. at 385 (no inference of fraud where "nothing explains why

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[16] Dr. Ruffolo's May 2007 stock sales were likewise made several months before the Company received the FDA approvable letter. *See* Chepiga Aff. Ex. 10.

these sales took place after a year of allegedly fraudulent statements . . . and seven months before any negative public disclosures); *Ressler*, 75 F. Supp. 2d at 60 ("[T]he stock sales at issue took place, for the most part, over six months prior to the release of the negative disclosure by [defendant.] Such timing does not suggest that the defendants meant to realize profits immediately prior to an expected and dramatic fall in the stock's price."); *City of Brockton Retirement System v. Shaw Group Inc.*, 540 F. Supp. 2d 464, 475-76 (S.D.N.Y. 2008) (finding that a "10-plus week gap" between defendants' sales and the company's disclosure of negative information was "not strongly suspicious").

Defendants' stock sales were also clustered during the week immediately following the Company's Third Quarter Earnings Call and the end of a blackout period prohibiting insiders from selling company stock. It is well-known that public companies such as Wyeth impose restrictions on the ability of their officers to trade company stock. *See In re Tyco Int'l Ltd.*, 185 F. Supp. 2d 102, 112 n.6 (D.N.H. 2002). These restrictions include the use of "blackout periods," during which trading is prohibited. These blackout periods necessarily bunch together insider stock sales into short periods of time. In addition, because "most publicly traded companies have adopted policies which prevent insiders from trading except during narrow windows that are open for only brief periods following the release of accounting information," courts have found that "evidence of insider trading following the release of accounting information is of limited value." *Id.* Here, the vast majority of Defendants' stock sales were made just after Wyeth's Third Quarter Earnings Call on October 19, 2006 and the end of a Company blackout period on October 20, 2006. *See* Compl. ¶ 80; Chepiga Aff. Ex. 14. As such, they were neither suspicious nor unusual. Indeed, that is when any sales were required to be done.

The volume of Messrs. Essner's, Mahady's, and Poussot's and Dr. Ruffolo's stock sales is also unsuspicious. Although Plaintiffs allege that these Defendants sold 70%, 97%, 89%, and 90% of their Company stock holdings, respectively, Compl. ¶¶ 125-26, 128-29, these numbers are wrong. They improperly fail to take into account vested stock options. *See In re Silicon Graphics Sec. Litig.*, 183 F.3d 970, 986-87 (9th Cir. 1999) ("[W]e see no reason to distinguish vested stock options from shares because vested stock options can be converted easily to shares and sold immediately. Actual stock shares plus exercisable stock options represent the owner's trading potential more accurately than the stock shares alone."); *In re Dura Pharms., Inc. Sec. Litig.*, No. 99 Civ. 0151-L, 2000 WL 33176043, at *10 (S.D. Cal. July 11, 2000) ("The Court also finds significant the evidence indicating that the Defendants did not exercise thousands of vested options and/or did not sell shares obtained through the exercising of the options."); *In re Blockbuster Inc. Secs. Litig*., No. 3 Civ. 0398-M, 2004 WL 884308, at *18 (N.D. Tex. Apr. 26, 2004) ("This percentage calculation takes into account vested stock options that were not exercised."); *Acito v. IMCERA Group*, 47 F.3d 47, 54 (2d Cir. 1995) ("The additional 30,000 shares that Kennedy sold in January represented less than 11% of his holdings; after the sale, Kennedy owned approximately 259,000 shares and/or options of IMCERA stock."). When vested stock options are factored in (as they must be), these Defendants' stock sales drop to less than 5%, 29%, 25%, and 45%, respectively.[17] *See* SEC Website.

If unvested options and restricted shares are considered, the percentages fall even further to less than 4%, 19%, 16%, and 27%, respectively. *See* SEC Website; *In re Astea Int'l Inc. Sec. Litig.*, No. 06 Civ. 1467, 2007 U.S. Dist. LEXIS 58238, at *42-43 (E.D. Pa. Aug. 8, 2007) ("[T]he fact that [the defendant] retained a majority of his holdings, if this court were to

[17] These percentages take into account all vested options, including in-the-money and out-of-the-money options, held by Defendants on the last day of the Class Period.

consider *vested and unvested* options, weakens any inference of motive to commit fraud.") (emphasis added).

These numbers are too low to raise an inference of scienter. *See, e.g.*, *In re Initial Pub. Offering Sec. Litig.*, 544 F. Supp. 2d 277, 294 (S.D.N.Y. 2008) (insider sales that represent less than 10% of the individual's total holdings are "insufficiently 'unusual' to permit an inference of scienter"); *In re eSpeed, Inc. Sec. Litig.*, 457 F. Supp. 2d 266, 291 (S.D.N.Y. 2006) (holding that sales of 10.9% and 17.4% of holdings were not unusual); *Keyspan*, 383 F. Supp. 2d at 382-83 (sale of less than 20% of available holdings not suspicious); *In re Vantive Corp. Sec. Litig.*, 283 F.3d 1079, 1092 (9th Cir. 2002) (sales of 38% of defendants' aggregate holdings not suspicious); *In re Dura*, 2000 WL 33176043, at *10 (sales of between 34-61% of holdings not sufficient to raise strong inference of fraud).

3. Mr. Martin's Stock Sales Were Not Suspicious or Unusual

The Complaint alleges that Mr. Martin sold 99% of his shares during the Class Period—in October 2006 as well as in April, May, and June 2007. Compl. ¶ 127. However, if unvested options and restricted shares are factored in, the percentage falls to less than 72%. *See* SEC Website. More importantly, both the timing and volume of Mr. Martin's sales are easily explained by his announcement on April 27, 2007 that he was leaving the Company. *See id.* Ex. 15. Pursuant to the Company's stock incentive plan, "any stock options not exercised prior to termination would have been forfeited." *Id.* Ex. 16. Mr. Martin was thus required to exercise his remaining options in the spring of 2007 or else lose them. Given these circumstances, the Complaint's factual allegations do not give rise to an inference that Mr. Martin acted with scienter. *See In re Health Mgmt. Sys. Sec. Litig.*, No. 97 Civ. 1865, 1998 WL 283286, at *6 n.3 (S.D.N.Y. June 1, 1998) (defendant's sales deemed unsuspicious because "[w]hile [they] were quite high during the Class Period, this was most likely on account of the fact that he resigned as

[a director] . . . and was divesting himself of his shares"); *In re LaBranche Sec. Litig.*, 405 F. Supp. 2d 333, 355-56 (S.D.N.Y. 2005) ("In light of the fact that [defendant] retired from [the corporation] . . . a divestiture of this size . . . is hardly suspicious.").

C. Plaintiffs Have Not Alleged Conscious Misbehavior or Recklessness

Plaintiffs also fail to allege facts "constituting strong circumstantial evidence of conscious misbehavior or recklessness." *Kalnit*, 264 F.3d at 138-39. The Second Circuit has established a high bar for meeting this standard; defendants' conduct must be "highly unreasonable" and "represent[] an extreme departure from the standards of ordinary care . . . to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *Rothman v. Gregor*, 220 F.3d 81, 90 (2d Cir. 2000). Moreover, where, as here, a plaintiff fails to establish motive, the "strength of the circumstantial allegations must be correspondingly greater. . . . Plaintiffs must specifically alleg[e] defendants' knowledge of the facts or access to information contradicting their public statements." *Bristol-Myers*, 312 F. Supp. 2d at 562 (citation omitted).

The Complaint fails to satisfy this stringent standard. Defendants' alleged misrepresentations pertain to the anticipated FDA approval of Pristiq for VMS and its potential revenue stream. Yet issuing positive statements about the projected success of a pipeline drug is, by its very nature, neither "highly unreasonable" nor "an extreme departure from the standards of ordinary care." As the court explained in *Bristol-Myers*, even where a drug company *has some indication* that a drug might not be approved, this fact is insufficient to allege scienter: "Given the uncertainty inherent in any application for FDA approval, Defendants' alleged 'inkling,' which is a 'hint,' 'suggestion' or 'slight indication' [that the FDA might not approve the drug], is reasonable and entirely consistent with Defendants' public statements. . . . It does not constitute strong circumstantial evidence of conscious misbehavior or recklessness." 312 F. Supp. 2d at

562; *see also AstraZeneca*, 2008 U.S. Dist. LEXIS 43680, at *46 (granting defendants' motion to dismiss because "[n]othing appears in the complaint showing that there was a consensus of management that the risks of [the drug] made [it] unlikely to be approved"); *Shields*, 25 F.3d at 1129 (2d Cir. 1994) ("[M]isguided optimism is not a cause of action, and does not support an inference of fraud. We have rejected the legitimacy of 'alleging fraud by hindsight.'"); *In re Eastman Kodak Co. Sec. Litig.*, No. 05 Civ. 6326, 2006 WL 3149361, at *4 (W.D.N.Y. Nov. 1, 2006) ("An even more stringent scienter requirement applies to forward-looking statements . . . where plaintiffs must plead facts to support the strong inference that the speaker had actual knowledge that the statement was false or misleading when made.").

As discussed previously, Plaintiffs have not alleged that Defendants knew during the Class Period that the FDA would not issue an approval letter for Pristiq in July 2007. *See supra* Section II.A. As such, the Complaint fails to give rise to an inference of conscious misbehavior or recklessness.

IV. PLAINTIFFS HAVE NOT ALLEGED LOSS CAUSATION

The Court should also dismiss the Section 10(b) and Rule 10b-5 claim because Plaintiffs fail to plead loss causation. As the Supreme Court stated in *Dura Pharmaceuticals, Inc. v. Broudo*, a decline in stock price may reflect any number of factors, including "changed economic circumstances, changed investor expectations, new industry-specific or firm-specific facts, conditions, or other events." 544 U.S. 336, 342-43 (2005). "Establishing loss causation is critical [to the success of a securities fraud claim] because Section 10(b) is not meant to 'provide investors with broad insurance against market losses, but to protect them against those economic losses that misrepresentations actually cause.'" *In re Rhodia S.A. Sec. Litig.*, 531 F. Supp. 2d 527, 544 (S.D.N.Y. 2007) (quoting *Dura*, 544 U.S. at 345). Thus to survive a motion to dismiss,

a complaint must allege "a causal connection between the material misrepresentation and the [alleged] loss." *Dura*, 544 U.S. at 342.

"One of the ways a plaintiff can plead loss causation is to allege that the market reacted negatively to a corrective disclosure regarding the falsity of the defendants' representations." *In re Winstar Communs.*, 01 Civ. 3014, 2006 WL 473885, at *13 (S.D.N.Y. Feb. 27, 2006) (citations omitted). This requires a "showing that plaintiff suffered an economic loss fairly attributable to the public airing of the alleged fraud, *i.e.*, a significant stock price decline immediately following the announcement that reveals the fraud to the public." *Id.; see also Winstar*, 2006 WL 473885, at *14 ("To establish loss causation by pleading a corrective disclosure, a plaintiff must allege that when truthful word revealing the falsity of defendant's representation reached the public, the market reacted negatively causing plaintiff to suffer an injury.").

Here, Plaintiffs allege that Defendants violated the securities laws by failing to disclose adverse safety data associated with Study 315. *See supra* Section II.B. As discussed previously, Defendants in fact disclosed this information at the May 2007 ACOG annual meeting, and the information was later discussed in an analyst report dated May 21, 2007. *Id*. Importantly, following the release of the May 21, 2007 analyst report, Wyeth's stock price stayed essentially the same. *Id.* Because the disclosure of the alleged omissions about Study 315 did not cause a drop in Wyeth's stock price, these omissions cannot be said to have "caused" Plaintiffs' loss. *See Rhodia*, 531 F. Supp. 2d at 545 (plaintiffs adequately plead loss causation only where they allege that "the value of their securities *dropped* immediately following defendants' announcement.") (emphasis added).

Moreover, the lack of market reaction in May 2007 to the safety data makes clear that the price drop that occurred on July 24, 2007 was due solely to disclosure of the *FDA's decision* on the Pristiq NDA. The Company's July 24, 2007 press release disclosed information that the Company had just learned the day before: that the FDA issued an approvable letter for the use of Pristiq to treat VMS and that the FDA required the Company to conduct additional clinical research. Chepiga Aff. Ex. 10. The law clearly states that "the loss causation requirement is satisfied only if the public disclosure causing injury addressed the specific fact allegedly concealed." *Rhodia*, 531 F. Supp. 2d at 545; *see also In re Worldcom, Inc. Sec. Litig.*, 02 Civ. 3288, 2005 WL 2319118, at *23 (S.D.N.Y. Sept. 21, 205) ("Unless [the plaintiff] can establish that his losses were attributable to some form of revelation to the market of the wrongfully concealed information, they are not recoverable in a private securities action.").

Although the July 24, 2007 press release discussed the Study 315 safety data to which the FDA was reacting, this information was not new. It had been disclosed previously. For a plaintiff to establish loss causation by alleging that the market reacted negatively to a corrective disclosure, "the disclosed fact must be new to the market." *In re Omnicom Group, Inc. Sec. Litig.*, No. 02 Civ. 4483, 2008 WL 243788, at *5 (S.D.N.Y. Jan. 29, 2008). "A recharacterization of previously disclosed facts cannot qualify as a corrective disclosure." *Id.* Because the safety data from Study 315 were disclosed to the market in May 2007, over two months before the press release was issued, they was not "new to the market" at the time they were subsequently referenced in a press release. For all of the above-stated reasons, Plaintiffs have failed to allege loss causation.

V. PLAINTIFFS FAIL TO STATE A CLAIM UNDER SECTION 20(a)

Plaintiffs also attempt to state a claim against all Defendants under Section 20(a) of the Exchange Act, which imposes joint and several liability on every person who "controls

any person liable under any provision of this chapter or of any rule or regulation thereunder." 15 U.S.C. § 78t(a) (2008). "To establish a *prima facie* case of control person liability, a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." *ATSI*, 493 F.3d at 108. Here, the Complaint fails to allege both a primary violation of the securities laws and culpable participation by the Defendants.

It is well-settled that "[i]n the absence of a primary violation, a plaintiff cannot state a claim for controlling person liability under § 20(a) of the Securities Exchange Act." *Salinger v. Projtectavision, Inc.*, 972 F. Supp. 222, 235 (S.D.N.Y. 1997); *see also ATSI*, 493 F.3d at 108 (dismissing Section 20(a) claim for failure to allege a primary violation). Because Plaintiffs fail to state a claim under Section 10(b), *see supra* Parts II-IV, and do not plead any other violations of the Exchange Act, Plaintiffs fail to state a claim under Section 20(a).

Moreover, a plaintiff must plead culpable participation "with the same particularity as scienter under Section 10(b). Namely, in order to withstand a motion to dismiss, a [S]ection 20(a) claim must allege, at a minimum, particularized facts of the controlling person's conscious misbehavior or recklessness." *Lapin v. Goldman Sachs Group, Inc.*, 506 F. Supp. 2d 221, 246; *see also Edison Fund v. Cogent Inv. Strategies Fund, Ltd.*, No. 06 Civ. 40450, 2008 WL 857631, at *16 (S.D.N.Y. Mar. 31, 2008); *Kalin v. Xanboo, Inc.*, 526 F. Supp. 2d 392, 406 (S.D.N.Y. 2007). As discussed above, Plaintiffs fail to plead with particularity facts giving rise to an inference that any of the Defendants acted with conscious intent or recklessness. *See supra* Part III. Their Section 20(a) claim thus fails.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court dismiss the Complaint in its entirety and with prejudice. Plaintiffs have already amended their complaint

once and no efforts at repleading will cure Plaintiffs' legally invalid claims. Because Plaintiffs' case rests on a non-actionable premise, the Complaint should be dismissed without further leave to amend. *See Jones v. N.Y. State Div. of Military & Naval Affairs*, 166 F.3d 45, 50 (2d Cir. 1998) ("[A] district court may properly deny leave when amendment would be futile.").

Dated: New York, New York
June 10, 2008

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Appendix A

CAUTIONARY LANGUAGE ACCOMPANYING DEFENDANTS' STATEMENTS

<table>
<tr><th colspan="2">SEC 10-K FILINGS: ITEM 1A. RISK FACTORS</th></tr>
<tr><th>Date</th><th>Cautionary Language</th></tr>
<tr><td>2005 (filed February 27, 2006)</td><td>Our future operating results may differ materially from the results described in this report due to the risks and uncertainties related to our business and our industry, including those discussed below. In addition, these factors represent risks and uncertainties that could cause actual results to differ materially from those implied by forward-looking statements in this report. We refer you to our "Cautionary Note Regarding Forward-Looking Statements," on page I-13 of this report, which identifies forward-looking statements in this report. The risks described below are not the only risks we face. Additional risk and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business, financial condition or results of operations.

Risks Associated with Development and Marketing of New Drugs

The development of novel pharmaceuticals, vaccines, and biotechnology products involves a lengthy and complex process, and we may be unable to commercialize, or be delayed in commercializing, any of our product candidates currently under development.

We have multiple product candidates in development and devote considerable resources to research and development activities, including clinical trials. These activities involve a high degree of risk and take many years. Our product development efforts with respect to any product candidate may fail, and we may be unable to commercialize it, for multiple reasons, including:
Failure of the product candidate in preclinical studies;
Difficulty enrolling patients in clinical trials;
Adverse reactions to the product candidate or indications of other safety concerns;
Insufficient clinical trial data to support the safety and/or effectiveness of the product candidate;
Our inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner; and
Our failure to obtain the required regulatory approvals for the product candidate or the facilities in which it is manufactured.</td></tr>
</table>

	The development and commercialization of novel drugs requires significant expenditures with a low probability of success. Successful development and commercialization of new pharmaceuticals, vaccines, and biotechnology products is expensive. Conducting Phase III clinical trials is particularly costly. If our large-scale clinical trials are not successful, we will not recover our substantial investments in applicable product candidates. Even where our clinical trials are sufficient to obtain product approval, we may not be able to achieve our anticipated product labeling, which could adversely impact the commercial success of the applicable product. The substantial funds we spend developing new products depress near-term profitability with no assurance that the expenditures will generate future profits to offset these costs.
2006 (filed February 26, 2007)	Our future operating results may differ materially from the results described or incorporated by reference in this report due to the risks and uncertainties related to our business and our industry, including those discussed below. In addition, these factors represent risks and uncertainties that could cause actual results to differ materially from those implied by forward-looking statements in this report. We refer you to our "*Cautionary Note Regarding Forward-Looking Statements*," on pages I-10 and I-11 of this report, which identifies forward-looking statements included or incorporated by reference in this report. The risks described below are not the only risks we face. Additional risk and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business, financial condition or results of operations. ***Risks Associated with Development and Marketing of New Drugs*** **The development of novel pharmaceuticals, vaccines, and biotechnology products involves a lengthy and complex process, and we may be unable to commercialize, or be delayed in commercializing, any of our product candidates currently under development.** We have multiple product candidates in development and devote considerable resources to research and development activities, including clinical trials. These activities involve a high degree of risk and take many years. Currently, we have a large number of product candidates in development. Our product candidates in late-stage development include four potential new products with respect to which we filed New Drug Applications (NDAs) with the FDA in 2006: **PRISTIQ** (for the treatment of vasomotor symptoms), **VIVIANT**, **TORISEL**, and bifeprunox. We also filed NDAs in 2005 for **PRISTIQ** (for the treatment of major depressive disorder) and **LYBREL**, and we expect to file a number of additional NDAs for potential new products and important new indications for existing products in 2007. Our product development efforts with

respect to any product candidate may fail or be delayed, and we may be unable to commercialize it or be delayed in commercializing it, for multiple reasons, including:

- Failure of the product candidate in preclinical studies;
- Difficulty enrolling patients in clinical trials;
- Adverse reactions to the product candidate or indications of other safety concerns;
- Insufficient clinical trial data to support the safety and/or effectiveness of the product candidate;
- Our inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner; and
- Our failure to obtain, or our experiencing delays in obtaining, the required regulatory approvals for the product candidate or the facilities in which it is manufactured.

Notably, clinical trial data are subject to differing interpretations and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate or a new indication for an existing product, regulatory authorities may not share our views and may require additional data or may deny approval altogether. Additionally, regulatory authorities in different countries often apply differing standards for the approval of product candidates and/or new indications for existing products, meaning that approval of a particular product candidate or new indication in one country may not be predictive of approval in other countries.

The development and commercialization of novel drugs requires significant expenditures with a low probability of success.

Successful development and commercialization of new pharmaceuticals, vaccines, and biotechnology products is expensive and inherently uncertain. Conducting late-stage clinical trials is particularly costly. If our clinical trials are not successful, we will not recover our substantial investments in applicable product candidates. Even where our clinical trials are sufficient to obtain product approval, we may not be able to achieve our anticipated product labeling, which could adversely impact the commercial success of the applicable product. The substantial funds we spend developing new products depress near-term profitability with no assurance that the expenditures will generate future profits to offset these costs.

SEC 10-Q FILINGS	
Date	**Cautionary Language**
August 7, 2006 November 6, 2006	This report includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "plan," "could," "may," "will," "believe," "estimate," "forecast," "project" and other words of similar meaning. These forward-looking statements address various matters, including: • Our anticipated results of operations, financial condition and capital resources; • Benefits from our business activities and transactions, productivity initiatives and facilities management, such as enhanced efficiency, reduced expenses, avoided expenditures and reduction of supply constraints; • Our expectations, beliefs, plans and strategies, anticipated developments and other matters that are not historical facts; including plans to continue our productivity initiatives and expectation regarding product demand and growth; • The resolution of the manufacturing issues at our Guayama, Puerto Rico manufacturing facility; • Anticipated receipt of, and timing with respect to, regulatory approvals and filings and product launches; • Anticipated developments relating to product supply and sales of our key products; • Sufficiency of facility capacity for growth; • Changes in our product mix; • Our ability to continue the shift of sales of **PROTONIX** from the Medicaid segment to the managed care segment; • Uses of borrowings under credit facilities and proceeds from debt issuances; • Timing and results of research and development activities, including those with collaborators;

	• Prospects for our product candidates; • Estimates and assumptions used in our critical accounting policies; • Costs related to product liability, patent protection, environmental matters, government investigations and other legal proceedings; • Opinions and projections regarding impact from, and estimates made for purposes of accruals for future liabilities with respect to, taxes, product liability claims and other litigation (including the diet drug litigation), environmental cleanup and other potential future costs; • Various aspects of the diet drug litigation; • Calculations of projected benefit obligations under pension plans, expected contributions to pension plans and expected returns on pension plan assets; • Assumptions used in calculations of deferred tax assets; • Future charges related to implementing our productivity initiatives; • Anticipated amounts of future contractual obligations and other commitments, including future minimum rental payments under non-cancelable operating leases and estimated future pension and other postretirement benefit payments; • The financial statement impact of changes in generally accepted accounting principles; • The projected impact of expensing stock options; • Plans to vigorously defend various lawsuits; • Our and our collaborators' ability to protect our intellectual property, including patents; • Minimum terms for patent protection with respect to various products; • Future impact of manufacturing documentation issues at certain European manufacturing sites;

- Impact of legislation or regulation affecting product approval, pricing, reimbursement or patient access, both in the United States and internationally;
- Impact of managed care or health care cost-containment;
- Impact of competitive products, including generics; and
- Impact of economic conditions, including interest rate and exchange rate fluctuation.

Each forward-looking statement contained in this report is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. These risks and uncertainties include risks associated with the inherent uncertainty of the timing and success of product research, development and commercialization (including with respect to our pipeline products); drug pricing and payment for our products by government and third party-payors; manufacturing (including government regulation of manufacturing operations); data generated on the safety and efficacy of our products; economic conditions including interest and currency exchange rate fluctuations; changes in generally accepted accounting principles; the impact of competitive or generic products; trade buying patterns; global business operations; product liability and other types of litigation; the impact of legislation and regulatory compliance; intellectual property rights; strategic relationships with third parties; environmental liabilities; and other risks and uncertainties, including those detailed from time to time in our periodic reports filed with the Securities and Exchange Commission, including our Current Reports on Form 8-K, Quarterly Reports on Form 10-Q and Annual Report on Form 10-K. In particular, we refer you to Item 1A. RISK FACTORS of our 2005 Annual Report on Form 10-K for additional information regarding the risks and uncertainties discussed above as well as additional risks and uncertainties that may affect our actual results. The forward-looking statements in this report are qualified by these risk factors.

We caution investors not to place considerable reliance on the forward-looking statements contained in this report. Each statement speaks only as of the date of this report (or any earlier date indicated in the statement), and we undertake no obligation to update or revise any of these statements, whether as a result of new information, future developments or otherwise. From time to time, we also may provide oral or written forward-looking statements in other materials. You should consider this cautionary statement and the risk factors identified under Item 1A. RISK FACTORS of our 2005 Annual Report on Form 10-K when evaluating those statements as well. Our business is subject to substantial risks and uncertainties, including those identified in this report. Investors, potential investors and others should give careful consideration to these risks and

	uncertainties.
May 9, 2007	This Quarterly Report on Form 10-Q includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "plan," "could," "may," "will," "believe," "estimate," "forecast," "project" and other words of similar meaning. These forward-looking statements address various matters, including: • Our anticipated results of operations, financial condition and capital resources; • Benefits from our business activities and transactions, productivity initiatives and facilities management, such as enhanced efficiency, reduced expenses and mitigation of supply constraints; • Our expectations, beliefs, plans, strategies, anticipated developments and other matters that are not historical facts, including plans to continue our productivity initiatives and expectations regarding growth in our business; • Future charges related to implementing our productivity initiatives; • Our expectations regarding compliance at our manufacturing facilities; • Anticipated receipt of, and timing with respect to, regulatory filings and approvals and anticipated product launches; • Emerging clinical data on our marketed and pipeline products and the impact on regulatory filings, market acceptance and/or product sales; • Anticipated developments relating to product supply, pricing and sales of our key products; • Sufficiency of facility capacity for growth; • Changes in our product mix; • Our ability to succeed in our strategy with certain products of focusing on higher value prescriptions within the third-party managed care segment; • Uses of cash and borrowings; • Timing and results of research and development activities, including those with collaboration partners; • Anticipated profile of, and prospects for, our product candidates; • Estimates and assumptions used in our critical accounting policies;

	• Costs related to product liability, patent litigation, environmental matters, government investigations and other legal proceedings; • Projections of our future effective tax rates, the impact of tax planning initiatives and resolution of audits of prior tax years; • Opinions and projections regarding impact from, and estimates made for purposes of accruals for future liabilities with respect to taxes, product liability claims and other litigation (including the diet drug litigation and hormone therapy litigation), environmental cleanup and other potential future costs; • Various aspects of the diet drug and hormone therapy litigation; • Calculations of projected benefit obligations under pension plans, expected contributions to pension plans and expected returns on pension plan assets; • Assumptions used in calculations of deferred tax assets; • Anticipated amounts of future contractual obligations and other commitments; • The financial statement impact of changes in generally accepted accounting principles; • Plans to vigorously defend various lawsuits; • Our and our collaboration partners' ability to protect our intellectual property, including patents; • Minimum terms for patent protection with respect to various products; • Impact of our settlement of patent litigation with Teva regarding **EFFEXOR XR** and the timing and impact of generic competition for **EFFEXOR** and **EFFEXOR XR**; • Timing and impact of generic competition for **ZOSYN/TAZOCIN**; • Impact of manufacturing process issues at certain manufacturing sites outside the United States; • Impact of minor process modifications relating to manufacture of the active ingredient in **TYGACIL**; • Impact of legislation or regulation affecting product approval, pricing, reimbursement or patient access, both in the United States and internationally; • Impact of managed care or health care cost-containment; • Impact of competitive products, including generics; and

- Impact of economic conditions, including interest rate and exchange rate fluctuation.

Each forward-looking statement contained in this report is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. These risks and uncertainties include: the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialization of our products, including with respect to our pipeline products; government cost-containment initiatives; restrictions on third-party payments for our products; substantial competition in our industry, including from branded and generic products; data generated on our products; the importance of strong performance from our principal products and our anticipated new product introductions; the highly regulated nature of our business; product liability, intellectual property and other litigation risks and environmental liabilities; uncertainty regarding our intellectual property rights and those of others; difficulties associated with, and regulatory compliance with respect to, manufacturing of our products; risks associated with our strategic relationships; economic conditions including interest and currency exchange rate fluctuations; changes in generally accepted accounting principles; trade buying patterns; the impact of legislation and regulatory compliance; risks and uncertainties associated with global operations and sales; and other risks and uncertainties, including those detailed from time to time in our periodic reports filed with the Securities and Exchange Commission, including our Current Reports on Form 8-K, Quarterly Reports on Form 10-Q and Annual Report on Form 10-K. In particular, we refer you to "Item 1A. RISK FACTORS" of our 2006 Annual Report on Form 10-K for additional information regarding the risks and uncertainties discussed above as well as additional risks and uncertainties that may affect our actual results. The forward-looking statements in this report are qualified by these risk factors.

We caution investors not to place undue reliance on the forward-looking statements contained in this report. Each statement speaks only as of the date of this report (or any earlier date indicated in the statement), and we undertake no obligation to update or revise any of these statements, whether as a result of new information, future developments or otherwise. From time to time, we also may provide oral or written forward-looking statements in other materials, including our earnings press releases. You should consider this cautionary statement and the risk factors identified under "Item 1A. RISK FACTORS" of our 2006 Annual Report on Form 10-K when evaluating those statements as well. Our business is subject to substantial risks and uncertainties, including those identified in this report. Investors, potential investors and others should give careful consideration to these risks and uncertainties.

CONFERENCE CALLS	
Date	**Cautionary Language**
July 12, 2006	[L]et me remind you that certain statements and comments that we make today are forward-looking statements, and therefore involve risks and uncertainties. These risks and uncertainties are more fully disclosed and described in our annual report on Form 10-K and our quarterly reports on Form 10- Q.
July 20, 2006	But before beginning, let me remind you that certain statements made today that are not historical facts are by their nature forward-looking and involve risks and uncertainties. Actual results may differ materially from such forward-looking information. This has been more fully disclosed in our press release and in our periodic SEC reports, including the quarterly reports on Form 10-Q and the annual report on Form 10-K.
October 19, 2006	Before beginning, let me remind you that certain statements made today that are not historical facts are, by their nature, forward-looking and involve risks and uncertainties. Actual results may differ materially from such forward-looking information. This has been more fully disclosed in our press release and our periodic SEC reports including quarterly reports on form 10-Q and the annual report on form 10-K.
January 30, 2007	Now as a reminder, certain statements that are made today that are not historical facts are, by their nature forward-looking and involve risks and uncertainties. Actual results may differ materially from such forward-looking information. This has been more fully disclosed in our press release and in our periodic SEC reports including quarterly reports on Form 10-Q and the annual report on Form 10-K.
July 19, 2007	Let me remind you that certain statements made today that are not historical facts are by their nature forward looking and involve risks and uncertainties, actual results may differ materially from such forward looking information. This has been more fully disclosed in our Press Release issued this morning and in our periodic SEC reports including quarter reports on form 10Q and the annual report on form 10K.

CONFERENCE PRESENTATIONS	
Date	**Cautionary Language**
October 5, 2006	The statements in these materials that are not historical facts are forwardlooking statements based on current expectations of future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include risks associated with the inherent uncertainty of the timing and success of product research, development and commercialization (including with respect to our pipeline products), drug pricing and payment for our products by government and third-party payers, manufacturing, data generated on the safety and efficacy of our products, economic conditions including interest and currency exchange rate fluctuations, changes in generally accepted accounting principles, the impact of competitive or generic products, trade buying patterns, global business operations, product liability and other types of litigation, the impact of legislation and regulatory compliance, intellectual property rights including the ability of any particular patent to provide market exclusivity, strategic relationships with third parties, environmental liabilities, and other risks and uncertainties, including those detailed from time to time in our periodic reports filed with the Securities and Exchange Commission, including our current reports on Form 8-K, quarterly reports on Form 10-Q and annual report on Form 10-K, particularly the discussion under the caption "Item 1A, Risk Factors." We assume no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.
January 9, 2007 February 7, 2007 March 13, 2007 June 12, 2007	The statements in this presentation that are not historical facts are forwardlooking statements based on current expectations of future events that involve risks and uncertainties including, without limitation, risks associated with the inherent uncertainty of pharmaceutical research, product development, manufacturing, commercialization, economic conditions including interest and currency exchange rate fluctuations, the impact of competitive or generic products, product liability and other types of lawsuits, the impact of legislative and regulatory compliance and obtaining approvals, and patent, and other risks and uncertainties, including those detailed from time to time in Wyeth's periodic reports, including quarterly reports on Form 10-Q and the annual report on Form 10-K, filed with the Securities and Exchange Commission. Quarterly results, in particular, can vary due to issues which include, but are not limited to, changes in exchange rates, the timing of actions taken by the Company to ensure long-term improvements to our manufacturing processes, the timing of regulatory approval of new products and/or facilities and the timing of promotional programs. Actual results may vary materially from the forward-looking statements. The Company assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

April 19, 2007	The statements in this presentation that are not historical facts are forward-looking statements based on current expectations of future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. In particular, the statements in this presentation regarding clinical data and/or the regulatory status of our pipeline products are based on a preliminary analysis of the data and our expectations as to how that data will impact the regulatory approval process, which is subject to risks and uncertainties related to both the timing and success of regulatory approval. In addition, although it remains our goal to resolve the issues raised in the Warning Letter relating to our Guayama, Puerto Rico facility as quickly as possible, we cannot exclude the possibility that these issues will result in further regulatory action or delays in the approval of new products or release of approved products manufactured at the facility. Other risks and uncertainties include the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialization of our products, including with respect to our pipeline products; government cost-containment initiatives; restrictions on third-party payments for our products; substantial competition in our industry, including from branded and generic products; data generated on our products; the importance of strong performance from our principal products and our anticipated new product introductions; the highly regulated nature of our business; product liability, intellectual property and other litigation risks and environmental liabilities; uncertainty regarding our intellectual property rights and those of others; difficulties associated with, and regulatory compliance with respect to, manufacturing of our products; risks associated with our strategic relationships; economic conditions including interest and currency exchange rate fluctuations; changes in generally accepted accounting principles; trade buying patterns; the impact of legislation and regulatory compliance; risks and uncertainties associated with global operations and sales; and other risks and uncertainties, including those detailed from time to time in our periodic reports filed with the Securities and Exchange Commission, including our current reports on Form 8-K, quarterly reports on Form 10-Q and annual report on Form 10-K, particularly the discussion under the caption "Item 1A, Risk Factors." The forward-looking statements in this presentation are qualified by these risk factors. We assume no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.
May 22, 2007	Good afternoon. Going to review a little bit about the pipeline and spend a good deal of time on the drugs that we have in registration. This of course is research and research is associated with risks and that is outlined in our forward-looking statements. The statements in this presentation that are not historical facts are forward-looking statements based on current

	expectations of future events that involve risks and uncertainties including, without limitation, risks associated with the inherent uncertainty of pharmaceutical research, product development, manufacturing, commercialization, economic conditions including interest and currency exchange rate fluctuations, the impact of competitive or generic products, product liability and other types of lawsuits, the impact of legislative and regulatory compliance and obtaining approvals, and patent, and other risks and uncertainties, including those detailed from time to time in Wyeth's periodic reports, including quarterly reports on Form 10-Q and the annual report on Form 10-K, filed with the Securities and Exchange Commission. Quarterly results, in particular, can vary due to issues which include, but are not limited to, changes in exchange rates, the timing of actions taken by the Company to ensure long-term improvements to our manufacturing processes, the timing of regulatory approval of new products and/or facilities and the timing of promotional programs. Actual results may vary materially from the forward-looking statements. The Company assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.
May 31, 2007	I will be making some forward-looking statements. They inherently may involve some risk and uncertainty and therefore I do direct you to our forward-looking statement. The statements in this presentation that are not historical facts are forward-looking statements based on current expectations of future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include risks associated with the inherent uncertainty of the timing and success of product research, development and commercialization (including with respect to the NDA filings for Wyeth's pipeline products referenced in this presentation), drug pricing and payment for Wyeth's products by government and third-party payers, manufacturing, data generated on the safety and efficacy of Wyeth's products, the impact of competitive or generic products, trade buying patterns, global business operations, product liability and other types of litigation, the impact of legislative and regulatory compliance, intellectual property rights, strategic relationships with third parties, environmental liabilities, and other risks and uncertainties, including those detailed from time to time in Wyeth's periodic reports filed with the Securities and Exchange Commission, including Wyeth's current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports on Form 10-K, particularly the discussion in Wyeth's 2005 annual report on Form 10-K under the caption "Item 1A, Risk Factors." Wyeth assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

PRESS RELEASES	
Date	**Cautionary Language**
June 26, 2006 January 23, 2007	The statements in this press release that are not historical facts are forward-looking statements based on current expectations of future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include risks associated with the inherent uncertainty of the timing and success of product research, development and commercialization (including with respect to our pipeline products), drug pricing and payment for our products by government and third party-payors, manufacturing, data generated on the safety and efficacy of our products, economic conditions including interest and currency exchange rate fluctuations, changes in generally accepted accounting principles, the impact of competitive or generic products, trade buying patterns, global business operations, product liability and other types of litigation, the impact of legislation and regulatory compliance, intellectual property rights, strategic relationships with third parties, environmental liabilities, and other risks and uncertainties, including those detailed from time to time in our periodic reports filed with the Securities and Exchange Commission, including our current reports on Form 8-K, quarterly reports on Form 10-Q and annual report on Form 10-K, particularly the discussion under the caption "Item 1A, Risk Factors." We assume no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.
October 5, 2006	The statements in this press release that are not historical facts are forward-looking statements based on current expectations of future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include risks associated with the inherent uncertainty of the timing and success of product research, development and commercialization (including with respect to our pipeline products), drug pricing and payment for our products by government and third-party payors, manufacturing, data generated on the safety and efficacy of our products, economic conditions including interest and currency exchange rate fluctuations, changes in generally accepted accounting principles, the impact of competitive or generic products, trade buying patterns, global business operations, product liability and other types of litigation, the impact of legislation and regulatory compliance, intellectual property rights, including the ability of any particular patent to provide market exclusivity, strategic relationships with third parties, environmental liabilities, and other risks and uncertainties, including those detailed from time to time in our periodic reports filed with the Securities and Exchange Commission, including our current reports on Form 8-K, quarterly reports on Form 10-Q and annual report on Form 10-K, particularly the discussion under the caption "Item 1A. Risk Factors." We assume no obligation to

	publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.
May 9, 2007	The statements in this press release that are not historical facts are forward-looking statements based on current expectations of future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. In particular, the statements in this press release regarding clinical data and/or the regulatory status of our pipeline products are based on a preliminary analysis of the data and our expectations as to how that data will impact the regulatory approval process, which is subject to risks and uncertainties related to both the timing and success of regulatory approval. Other risks and uncertainties include the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialization of our products, including with respect to our pipeline products; government cost-containment initiatives; restrictions on third-party payments for our products; substantial competition in our industry, including from branded and generic products; data generated on our products; the importance of strong performance from our principal products and our anticipated new product introductions; the highly regulated nature of our business; product liability, intellectual property and other litigation risks and environmental liabilities; uncertainty regarding our intellectual property rights and those of others; difficulties associated with, and regulatory compliance with respect to, manufacturing of our products; risks associated with our strategic relationships; economic conditions including interest and currency exchange rate fluctuations; changes in generally accepted accounting principles; trade buying patterns; the impact of legislation and regulatory compliance; risks and uncertainties associated with global operations and sales; and other risks and uncertainties, including those detailed from time to time in our periodic reports filed with the Securities and Exchange Commission, including our current reports on Form 8-K, quarterly reports on Form 10-Q and annual report on Form 10-K, particularly the discussion under the caption "Item 1A, Risk Factors." The forward-looking statements in this press release are qualified by these risk factors. We assume no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

APPENDIX B

15 U.S.C. § 78u-5

(i) Definitions. For purposes of this section, the following definitions shall apply:

(1) Forward-looking statement. The term "forward-looking statement" means—

(A) a statement containing a **projection of revenues**, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;

(B) a statement of the plans and objectives of management for future operations, including plans or **objectives relating to the products** or services of the issuer;

(C) a statement of **future economic performance**, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission;

(D) any statement of the **assumptions** underlying or relating to any statement described in subparagraph (A), (B), or (C);

(E) any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer; or

(F) a statement containing a **projection or estimate** of such other items as may be specified by rule or regulation of the Commission.